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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/810,230 | 03/27/2004 | Gary K. Michelson | 101.0113-01000 | 9461 |
| 22882 | 7590 | 10/31/2005 | EXAMINER | |
| MARTIN & FERRARO, LLP 1557 LAKE O'PINES STREET, NE HARTVILLE, OH 44632 | | | SHAFFER, RICHARD R | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 3733 |

DATE MAILED: 10/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|--------------------------------|--------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/810,230 | MICHELSON, GARY K. |
| | Examiner Richard R. Shaffer | Art Unit 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 October 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-46 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-46 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 March 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/27/04, 8/23/04, 9/12/04, 10/12/04
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Information Disclosure Statement

The Information Disclosure Statement filed on March 26, 2004 has citations not considered by the examiner. The SPINAL CONCEPTS Brochure, ORTHO DEVELOPMENT Brochure, and OSTEOTECH Brochure have not had a copy submitted for examination and thus have not been considered.

Drawings

The drawings are objected to because they are replete with errors for example:

- Reference character **128** is used in two different areas for “tool-engagement area” in **Figure 2**. Examiner believes one should be **142** instead.
- Reference characters for embodiments **300+** consistently have numerals in the figures not addressed in the specification.
- **Figure 12** does not clearly point out the ramped surface or vertical wall in a ratchet.

Corrected drawing sheets in compliance with 37 CFR 1:121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because on page 15, "ratcheting 150" should be "ratcheting 152". Appropriate correction is required.

Claim Objections

Claim 23 is objected to because of the following informalities: It contains the phrase "the wherein" which does not support the rest of the claim. It has been interpreted as though it was not there. Appropriate correction is required.

Claim Rejections - 35 USC § 101

Claim 41 is rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. The addition of genes coding for the production of bone in a fusion implant is not functional different than the equivalent fusion implant without the genes coding for the production of bone. Genes are required to be within a cell (the nucleus) for transcription to take place (production of RNA). Once RNA has been produced, then it can be translated by ribosomes into protein. One could see how RNA could enhance bone growth because it only needs to be present in the cytoplasm.

However, it still is impractical due to the unstable nature of RNA. This is why current practice focuses bone morphogenetic proteins or growth factors. Growth factors are useful because they enhance gene expression of bone producing genes.

Applicant will have to provide laboratory data demonstrating the usefulness of claimed invention should applicant feel the examiner is incorrect in the above paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-22, 24-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Biedermann, et al (US Patent 5,964,762).

Biedermann, et al disclose a bone plate for use on the spine. From the structure, it appears to be appropriate for an anterior surgical procedure although Biedermann, et al are silent as to what levels of the spinal column it is to be used on and whether or not it is anterior or posterior. The plate has three bone plate segments (1, 2, and 7) which is integrally formed with 2) capable of being moved towards and away from each other along the longitudinal axis. Fasteners (17) connect segments (1 and 2) together and is capable of being detached. There are at least two bone screws inserted through both segments at holes 8, 9, 15, and 16. They are locked by a securing screw (31) and base (32).

Biedermann, et al discloses (column 1, Lines 43-49) that the invention is capable of use for distraction or contraction. Column 4, Lines 3-17 disclose that the plates are first moved to determine positioning, then the anchor screws are set, then distraction/contraction occurs, and then finally the screws are locked. In Column 3, Lines 5-42, an instrument is taught to incrementally (by threads) compress or distract the bone plate segments. Applicant loosely used the term "instrument" to refer to both a gripping element and a tightening element. Due to using screws, it would be inherent to use a tightening element and to rotate the fasteners.

In regard to claims 20-22, there are two interpretations possible. One, the fastener may not be engaged with the lower plate, and once lowered slightly, will engage the lower plate and inhibit movement in the transverse direction but still allow movement in the longitudinal direction. The other interpretation is that the screw is engaged with both plates and when tightened forces the plates together inhibiting all movement.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 27, 28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann, et al. In regard to claim 23, it is already disclosed one would use the device for contraction or distraction. Ideally, with a device prone to

sliding, one would supply a plurality of lengths for use by a surgeon. This would allow him to position the screw at one of the ends of the slots so that it could only slide towards or away from the other plate. It is also well known in the art to provide implants that fit anatomically to a patient. Thus various configurations of curvate would be well within the practice and ability of one of ordinary skill in the art.

Claims 32-40 and 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Biedermann, et al in view of Bacelli (US Patent 6,306,136) and in further view of common knowledge in the art. All of the claimed limitations were disclosed in Biedermann, et al except the device in conjunction with an interbody spinal fusion implant. Bacelli teaches (Column 1, Paragraph 4) that is well known to use a bone fusion implant made of hydroxyapatite, bone graft, or bone substitutes. One of ordinary skill in the art would also have found it obvious to use an artificial implant, use bone morphogenetic protein, bioresorbable material (if the fusion alone would be enough support), using a substance to inhibit scar tissue formation, as well as coating, treating, or combining the plate with an antimicrobial material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on 7-5 (Mon-Fri, every other Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard Shaffer
Richard Shaffer
10/26/2005

David O. Reip
DAVID O. REIP
PRIMARY EXAMINER